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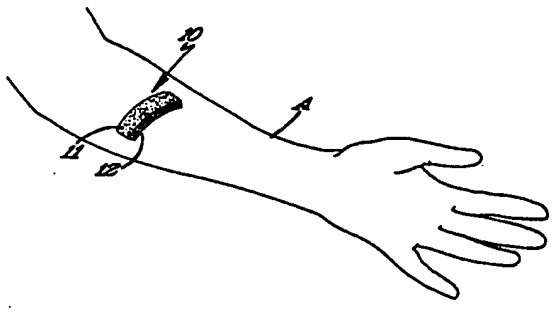
(54) Improved bandage containing a medicament.

(57) A flexible, liquid-absorbent, adhesive bandage includes a backing element and a substrate attached to the backing element. The substrate comprises a homogeneous, hydrophilic, stable matrix including a solid phase formed of a synthetic polymer and/or a long chain polysaccharide, or a combination thereof. The liquid phase of the matrix consists of a hydric alcohol, carbohydrates and/or proteins in an aqueous solution, and/or a combination thereof. The matrix contains a medicament therein for release to the affected areas.



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IMPROVED BANDAGE CONTAINING A MEDICAMENT

BACKGROUND OF THE INVENTION

This invention relates to an improved bandage which contains a medicament that is topically released into the skin. The application is a continuation in part application of my co-pending application, Serial No. 173,001, filed on July 28, 1980, and entitled "Sterile Improved Bandage Containing a Medicament".

Attempts have been made to develop bandages which are self-adhesive, absorbent, and sterile. For example, U.S. Patent No. 3,339,546 discloses a self-adhesive bandage which is adapted to adhere to moist surfaces such as the moist mucosa of the oral cavity. However, one of the essential materials of this self-adhesive bandage is an adhesive gum, preferably polyisobutylene, which is hydrophobic. Similarly, U.S. Patent Nos. 3,598, 122 and 3,596,123 disclose bandages which contain drugs that are continually released from an adhesive layer. These bandages are formed of layered materials which have drugs encapsulated in the adhesive layer. Even though the bandage disclosed in there prior art patents are said to be self-adhesive and are satisfactory vehicles for drugs, specific process steps are required for encapsulating or stratifying the drugs.

SUMMARY OF THE INVENTION

Therefore, it is a general object of this invention to provide a self-adhesive, novel bandage in which a medicament is molecularly dispensed for release to the affected area. The bandage is comprised of a flexible backing element and a self-adhesive substrate which becomes increasingly

tacky in the presence of moisture and which absorbs liquid and releases the medicament to the affected area while remaining dimensionally stable.

These and other objects and advantages of this invention will more fully appear from the following description made in connection with the accompanying drawings, wherein like reference characters refer to the same or similar parts throughout the several views.

FIGURES OF THE DRAWINGS

Fig. 1 is a perspective view illustrating the novel bandage applied to the arm of a patient.

Fig. 2 is a perspective view of a bandage illustrated in Fig. 1.

Fig. 3 is a perspective view of a bandage used as a surgical dressing.

Fig. 4 is a cross-sectional view taken approximately along line 4-4 of Fig. 2 and looking in the direction of the arrows.

Fig. 5 is a modified form of the bandage.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The bandage of the present invention has adhesive properties for maintaining contact with the skin, as well as possessing a certain amount of elasticity for movement with the skin. The bandage is intended to be easily handled and is non-irritating to the patient.

Referring now to the drawings, it will be seen that the bandage of the present invention is thereshown. The bandage, designated generally by the reference numeral 10, includes a backing member 11 and a self-adhesive substrate 12

which is secured to one end surface of the backing. The backing element 11 and the substrate 12 are both illustrated as rectangular sheets of material of uniform thickness. It is pointed out that the bandage 10 is intended to be regular in shape but may have any other configuration although the rectangular shape is preferred. In use, the bandage is applied with the substrate 12 in direct contact with the skin to cover a non-surgical wound, a surgical wound, or burned tissue. In Fig. 3, the embodiment illustrated therein is a surgical dressing and will be applied to the patient to cover a surgical wound.

Referring now to Fig. 5, it will be seen that a different embodiment of the bandage, designated generally by the reference numeral 10a, is thereshown. The bandage includes a pressure-sensitive adhesive element 11a which serves as the backing element and also serves as the means for securing the bandage to the surface of the skin. The pressure-sensitive adhesive element 11a may be formed of any of the materials used in commercially available adhesive elements such as a foam-tape adhesive element. It will be appreciated that most of the commercially available adhesive elements maintain an excellent bond with the skin and are not irritable with respect to the skin.

Primary to the unique structure of the bandage is the hydrophilic adhesive properties of the substrate which enhance the adhesion thereof to the skin. The substrate not only absorbs moisture, making it ideal for use as a surgical dressing, but the substrate becomes tackier as it absorbs moisture.

The substrate 12 may be formed from naturally occurring materials such as gum karaya, guar gum, gum acacia,

locust bean gum, and other polysaccharides. The substrate may also be formed from synthetic polymers such as polyacrylamide and its cogeners, such as methylene-Bis-acrylamide, polyacrylic acid molecular weights 250,000, 450,000, 1,000,000, and 4,000,000, and polyacrylamide sold under such trademarks as Reten by Hercules Company. When monomers such as acrylic acid or acrylamide are polymerized, it is necessary to use activators. Activators, which are used during polymerization, may include ferrous sulfate, sodium metabisulfite, potassium persulfate, as set forth in my co-pending application, Serial No. 58,684. The disclosure of my co-pending application, Serial No. 58,684, is incorporated by reference herein.

The synthetic polymers and/or natural gums and other polysaccharides constitute the solid phase of the matrix. The liquid phase of the matrix preferably consists of hydric alcohols such as glycerol or propylene glycol. Solutions or emulsions of saccharides and/or polysaccharides and/or proteins may be used in forming the matrix. Alternatively, a combination of a solution or emulsion of polysaccharides, saccharides, or proteins may be used in the liquid phase of the matrix.

The substrate 11 which is a stable matrix includes a solid phase comprising a synthetic polymer mixture, a karaya matrix, or a matrix of karaya and synthetic polymer. The solids of the matrix comprise 15% to 50% by weight of the matrix 11. The substrate may be sterilized. If the substrate is sterilized, the combination of the mixture is subjected to irradiation (usually gamma rays) of 2.5 mega rods for sterilization. Heretofore, this magnitude of irradiation to mixtures of polysaccharides, such as karaya with a hydric alcohol, preferably glycerol, would cause the matrix to lose dimensional stability with only slight pressure and/or water absorption.

This causes the matrix to become so tacky that it is not manageable as a surgical bandage. Further, if this irradiated karaya is used as a sterile pad to seal drainage as noted in the Hollister Patent No. 3,640,741, it may readily break down to a gelatinous substance which may run and break the seal.

The liquid phase of the matrix, such as hydric alcohol, comprises 30% to 70% by weight of the matrix.

The bandage also includes a suitable backing member which may include cotton fabric, woven or standard paper, synthetic fabrics, and/or plastics. Suitable synthetic fabrics may include nylon or polyester while a suitable plastic backing may include mylar or saran. When the bandage 10 is used as a surgical dressing, the backing element comprises a pervious material such as cotton fabric to permit diffusion of the absorbed liquid into the air.

The substrate 12 also contains a medicinal substance for release to the surface to which the bandage is applied. The medicinal substance is molecularly dispersed in the matrix rather than being encapsulated as in the prior art. The medicinal substance may include an antibacterial, antiseptic, or antifunginal agents such as boric acid, bacitracin, acriflavin, formaldehyde, gential violet, mercuric sulfide, mercurochrome, neomycin, and iodine. Nitroglycerine may be used as a coronary vaso dilater agent and hydrocortisone may be used as an anti-inflammatory agent. Suitable antipruretic agents include benzoin, calamine, camphor, menthol, phenol, and sulfur. The substrate may also include fragrances such as cinnamon oil, fir needle oil, lemon oil, peppermint oil, and spearmint. Suitable healing agents include allantoin, Peruvian balsam, Vitamin A, and Vitamin E. Hormonal agents may include

estrogen, progesterone, and testosterone. Protective agents may include benzoin, charcoal, talc, and zinc oxide. Salicylic acid is a suitable keratolytic agent and methyl salicylate is a suitable rubefacient. An exemplary antihistamine is chlorpheniramine.

The bandage also includes a suitable backing member which may include cotton fabric, woven or standard paper, synthetic fabrics, and plastics. Suitable synthetic fabric may include nylon or polyester while a suitable plastic backing may include mylar or saran.

When karaya or other natural gums are used in forming the matrix, it is necessary to use polyacrylic acid and/or polyacrylamide to protect or compensate degredation of karaya during irradiation, if the matrix is to be sterilized. However, a predetermined concentration of salts, such as aluminum sulfate or sodium chloride, may be used in the matrix with karaya in some instances in lieu of polyacrylamide and/or polyacrylic acid. For example, concentrations of approximately 6% sodium chloride or aluminum sulfate may be used with karaya in forming the solid phase of the matrix.

It has be found that vinyl acetate dioctyl maleate copolymer may also be advantageously used in forming the solid phase of the matrix. Vinyl acetate dioctyl maleate copolymer (sold under the trademark "Flexbond 150" by Air Products and Chemicals, Inc., and sold under the trademark "Bostik 8761" by the Bostik Company, Inc.) will intensify the tackiness of the bandage.

Another important gum material which may be used in forming the matrix is a starch graft copolymer sold under the trade name SGP 502S Absorbent Polymer by the Henkel Corporation, St. Paul, Minnesota. The starch graft copolymer product is

derived from corn starch and acrylonitrile and is a graft terpolymer of starch, acrylamide and sodium acrylate. The technical name for this starch graft copolymer product is starch-g-poly (acrylamide-co-sodium acrylate). The starch-g-poly material may be used alone to form the substrate or it may be used in combination with a synthetic gum such as acrylamide or a natural gum such as karaya. The starch-g-poly material is very effective as the skin contacting substrate since it does maintain its structural integrity and is non-toxic.

Example 1

	Nominal Amounts of Ingredients	Range of Ingredients
Polyacrylamide	5%	1-50%
Karaya	38%	5-45%
Glycerol	55%	30-70%
Povidone-Iodine	2%	0.1-10%

Example 2

Polyacrylic acid	10%	2-40%
Polyacrylamide	10%	2-40%
Karaya	18%	5-45%
Glycerol	60%	30-70%
Povidone-Iodine	2%	0.1-10%

Example 3

Polyacrylamide	15%	2-40%
Polyacrylic acid	15%	2-40%
Glycerol	68%	30-70%
Povidone-Iodine	2%	0.1-10%

Example 4

Polyacrylamide	30%	2-40%
Glycerol	62%	50-70%
Methyl salicylate	8%	0.1-15%

Example 5

Polyacrylamide	21.5%	2-40%
Polyacrylic acid	12.5%	2-40%
Glycerol	42%	30-70%
Vinyl acetate-dioctyl maleate	16%	10-20%
Methyl salicylate	8%	0.1-15%

Example 6

Polyacrylamide	32%	2-40%
Glycerol	55%	30-70%
Water	6%	1-10%
Methyl salicylate	8%	0.1-15%

Example 7

Povidone-Iodine	2%	0.1-10%
Hydroxy-propylcellulose (Klucel)	6%	0.1-10%
Glycerin	56%	30-70%
Water	6%	0.1-10%
Polyacrylamide (Reten 421)	30%	2-40%

Example 8

	Nominal Amounts of Ingredients	Range of Ingredients
Povidone-Iodine	10%	0.1-15%
Reten 421 (polyacrylamide)	5%	2-40%
Karaya	35%	5-45%
Glycerol	50%	30-70%

Example 9

Povidone-Iodine	2%	0.1-10%
Karaya	42%	5-45%
Glycerol	55%	30-70%

Example 10

Camphor	2%	0.1-5%
Methylenebisacrylamide	3%	0.1-10%
Acrylic acid	8%	0.1-10%
Glycerol	86%	45-90%
Activators*	1%	0.1-2%

*Potassium persulfate 0.6%
Sodium metabisulfite 0.2%
Ferrous sulfate 0.1%

Example 11

Camphor	2%	0.1-5%
Glycerol	5%	30-70%
Karaya	43%	5-45%

Example 12

Methyl salicylate	2%	0.1-10%
Methylene bisacrylamide	5%	0.1-10%
Acrylic Acid	8%	0.1-10%
Glycerol	84%	30-70%
Activators	1%	0.1-2%

Example 13

Methyl salicylate	8%	0.1-15%
Acrylic acid	2%	0.1-10%
Methylenebisacrylamide	1%	0.1-10%
Glycerol	48%	30-70%
Karaya	40%	5-45%
Activators	1%	0.1-2%

Example 14

	Nominal Amounts Of Ingredients	Range of Ingredients
Methyl salicylate	8%	0.1-15%
Karaya	45%	5-45%
Glycerol	47%	30-70%

Example 15

Vinyl acetate dioctyl maleate copolymer	62%	50-75%
Vinyl acetate ethylene	29%	25-50%
NaCl	1%	1-5%
Methyl salicylate	8%	0.1-15%

Example 16

Vinyl acetate dioctyl maleate	84%	80-98%
Karaya	12%	5-45%
NaCl	2%	0.5-5%
Povidone-Iodine	2%	0.1-10%

Example 17

Starch-g-poly	30%	15-50%
Glycerol	62%	30-70%
Nitroglycerine	8%	0.1-15%

Example 18

Starch-g-poly	25%	1-30%
Glycerol	55%	30-70%
Karaya	12%	5-45%
Nitroglycerine	8%	0.1-15%

WHAT IS CLAIMED IS:

1. A flexible, liquid-absorbent, adhesive bandage to be applied to a patient, comprising:

a flexible backing element selected from the group comprised of cotton, paper, synthetic fabric, and plastic,

a substrate attached to said backing element comprising a homogeneous, hydrophilic, stable matrix being sufficiently pliant to conform to the shape of the body contours, said matrix including a solid phase comprising about 15% to 50% of the total weight of the matrix and formed from a hydrophilic high-molecular polysaccharide and/or synthetic gum selected from the group comprising polyacrylic acid, polyacrylamide, and their cogeners, vinyl acetate ethylene copolymer, vinyl acetate dioctyl copolymer, natural gums, and starch-g-poly, and a liquid phase consisting of a solution or emulsion selected from the group comprising carbohydrate, protein, and hydric alcohol, and comprising from 30% to 70% by weight of the matrix, said matrix containing a medicament selected from the group including vaso dilators, an antibacterial agent, antiseptic agent, antifungal agent, antihistamine agent, anti-inflammatory agent, antipruretic agent, hormonal agent, keratolytic agent, skin protective agent, and a rubefacient agent, said bandage having an adhesive surface for contact with and adhesion to a patient's skin;

2. The bandage as defined in claim 1 wherein said liquid phase comprises a solution of a polysaccharide;

3. The bandage as defined in claim 1 wherein said liquid phase comprises a hydric alcohol such as glycerol;

4. The bandage as defined in claim 1 wherein the solid phase of matrix includes a natural gum selected from the group comprising gum karaya, gum acacia, locust bean gum, and guar gum;

5. The bandage as defined in claim 4 wherein said liquid phase comprises glycerol;

6. The bandage as defined in claim 4 wherein said matrix is comprised of 5% to 45% by weight of gum karaya, 2% to 40% by weight of polyacrylamide, and 30% to 70% by weight of glycerol;

7. The bandage as defined in claim 1 wherein said matrix is comprised of 10% to 50% by weight of polyacrylamide and 30% to 70% by weight of glycerol;

8. The bandage as defined in claim 1 wherein said matrix is formed of 2% to 40% by weight of polyacrylamide and 2% to 40% by weight of polyacrylic acid, and 30% to 70% by weight of glycerol;

9. The bandage as defined in claim 1 wherein said matrix is formed of 2% to 50% by weight of polyacrylic acid and 30% to 70% by weight of glycerol;

10. The bandage as defined in claim 3 wherein said medicament comprises 0.1% to 15% by weight of povidone-iodine;

11. The bandage as defined in claim 3 wherein said medicament comprises 0.1% to 5% by weight of camphor;

12. The bandage as defined in claim 4 wherein said medicament comprises 0.1% to 5% by weight of camphor;

13. The bandage as defined in claim 3 wherein said medicament comprises 0.1% to 15% by weight of methyl salicylate;

14. The bandage as defined in claim 1 wherein said matrix has adhesive properties whereby the surface which contacts the skin defines said adhesive surface;

15. The bandage as defined in claim 1 wherein said backing element is a pressure-sensitive adhesive element and defines said adhesive surface which contacts the patient's skin.

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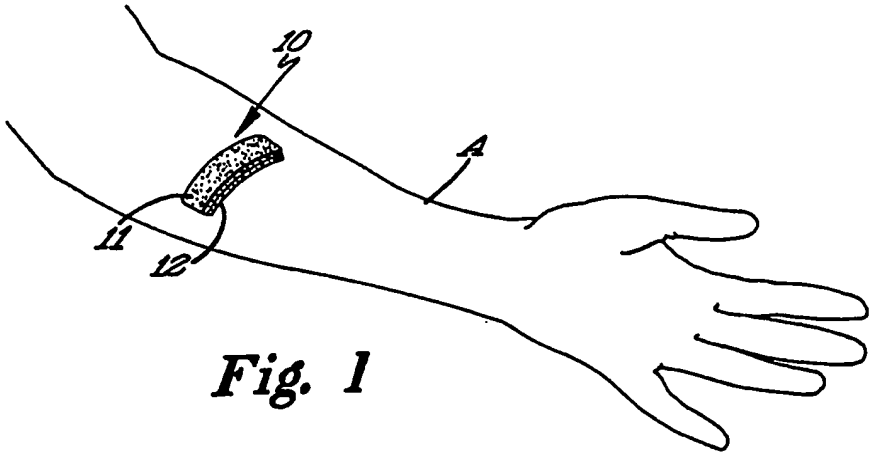

Fig. 1

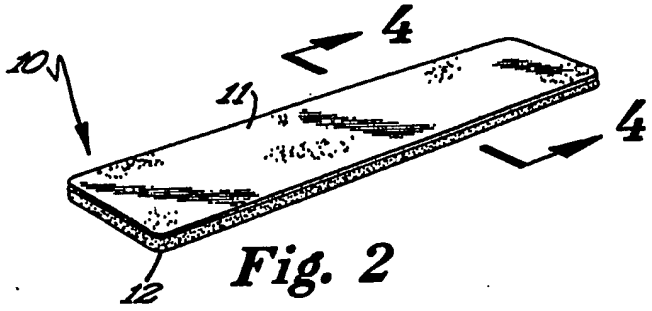

Fig. 2

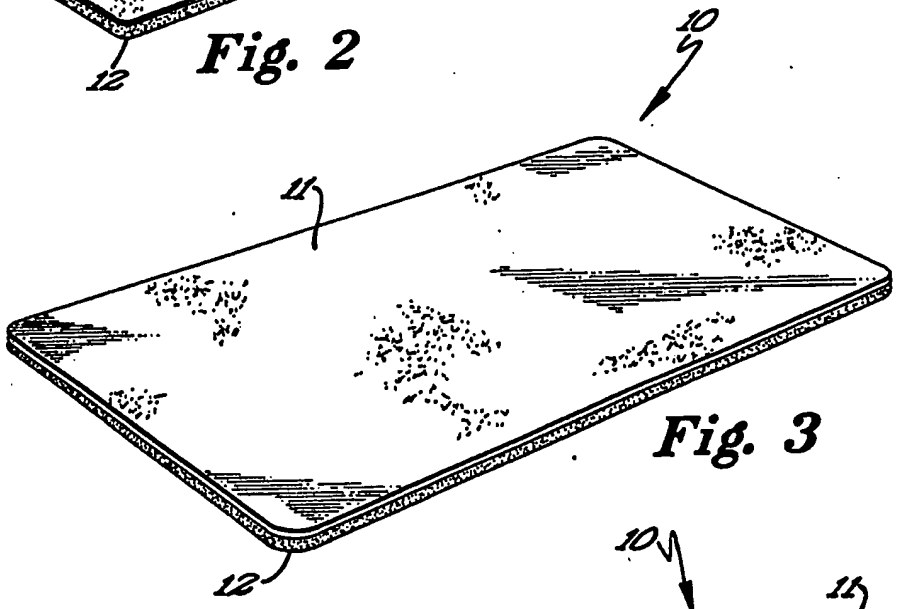

Fig. 3

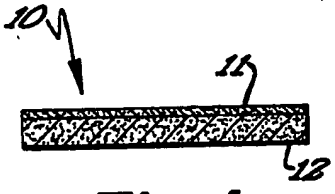

Fig. 4

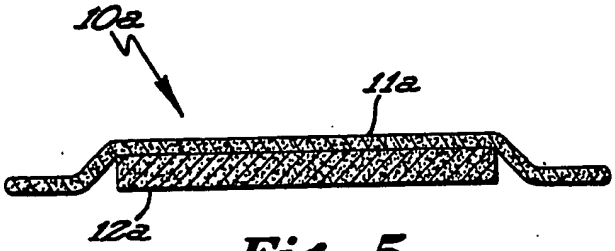

Fig. 5